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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,576	07/17/2000	HANS CHRISTIAN THOGERSEN	THOGERSEN=1	1127

7590 12/14/2005

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EXAMINER
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CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/445,576

Applicant(s)

THOGERSEN ET AL.

Examiner

Karen A. Canella

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 68-105, 108-111 and 113-139 is/are pending in the application.
- 4a) Of the above claim(s) 92-97, 100, 101, 104 and 105 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 68-72, 74, 78-91, 98, 99, 102, 103, 108-111, 113-116, 118 and 122-139 is/are rejected.
- 7) ☐ Claim(s) 73, 75-77, 117, 119-121 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

Art Unit: 1643

### **DETAILED ACTION**

Claims 1-67 have been canceled. Claims 68, 73-77, 108, 113, 117-121, 124, 126 and 127 have been amended. Claims 106, 107 and 112 have been canceled. Claims 135-139 have been added. Claims 68-105, 108-111 and 113-139 are pending. Claims 92-97, 100, 101, 104 and 105, drawn to non-elected inventions, remain withdrawn from consideration. Claims 68-91, 98, 99, 102, 103, 108-11 and 113-139 are under consideration.

Sections of Title 35, U.S. Code not found in this action can be found in a prior action.

Claim 78, 79, 122 and 123 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear how claim 78 further limits the scope of claim 75 which requires the specific sequence of SEQ ID NO:71 and which sequence fulfills the specific embodiments of the motif of SEQ ID NO:40. Claim 78 requires the substitution of at least one amino acid residue at positions 21, 22, 24, 25, 27, 28, 31, 32, 35, 39, 41 and 42, and thus would not fulfill the specific embodiment of SEQ ID NO:70. Claim 79 requires that the amino acid residue no. 6 of exon 1, is substituted by any non-helix breaking residue, and thus the claim could not fulfill the embodiment of SEQ ID NO:71 and could not further limit claim 77.

By analogy, with the analysis above, it is unclear how claims 122 and 123 further limit claims 119 and 121 which requires the specific sequence of SEQ ID NO:71.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 68-72, 74, 78-91, 98, 99, 102, 103, 108-111, 113-116, 118, 122-139 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description

Art Unit: 1643

requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(A) As drawn to inadequate written description of a genus of compounds

Claims 68-72, 74, 78-91, 98, 99, 108-111 are drawn to a trimeric polypeptide complex comprising three monomer polypeptides wherein each of said monomer polypeptides comprises a TTSE, wherein said TTSE has at least 98% amino acid sequence identity to SEQ ID NO:40, and wherein at least one of said monomer polypeptides is covalently linked to at least one heterologous moiety, and wherein said complex remains a trimer at temperatures of at least 60 degrees C. Claims 78 and 79 are included with this group because they are broader in scope than the trimeric polypeptide complex wherein the monomer polypeptides comprise SEQ ID NO:71.

Claims 113-116, 118, 122-139 are drawn to a monomer polypeptide construct comprising at least one TTSE, wherein said TTSE has at least 98% amino acid sequence identity to SEQ ID NO:40, and wherein at least one of said monomer polypeptides is covalently linked to at least one heterologous moiety, and wherein said complex remains a trimer at temperatures of at least 60 degrees C. Claims 122 and 123 are included with this group because they are broader in scope than the monomer polypeptide comprising SEQ ID NO:71.

SEQ ID NO:40 is a sequence motif which designates a genus of sequences in the TTSE, such that 21 positions out of the 36-mer motif are variable. Both the base claim for the TTSE monomer and the trimeric polypeptides comprising the TTSE monomer are drawn to a polypeptide having at least 68% sequence identity to SEQ ID NO:40. However, SEQ ID NO:40 allows for only about 42% sequence identity to any given amino acid as only 15 positions are specified within the motif. Thus the genus of compounds encompassed by the claims to a TTSE monomer having at least 68% sequence identity to SEQ ID NO:40 and a trimeric polypeptide comprising said TTSE monomer is highly variant. The disclosure of SEQ ID NO:40 as the sequence motif of said TTSE fails to adequately describe the genus because the genus tolerates members which do not bear any structural similarity to SEQ ID NO:40 as a sequence which has at least 68% identity to a sequence which allows 59% variability (21 residues out of 36 are "X"). One of skill in the art would reasonably conclude that applicant was not in possession of the claimed trimeric polypeptide complexes or trimerizing structural elements.

Art Unit: 1643

(B)As drawn to new matter

Claims 108 and 127 have been amended to recite a “lectin” as a ligand binding structure. The specification as filed does not contemplate a lectin as a ligand binding structure. One of skill in the art would conclude that applicant was not in possession of the inventions of claims 108 and 127 as drawn to a lectin.

Claims 68-72, 74, 78, 79, 80-91, 98, 99, 102, 103, 108-111, 113-116, 118, 122, 123-139 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for trimeric polypeptide complexes comprising a TTSE of SEQ ID NO:40 and a monomer polypeptide construct comprising a TTSE of SEQ ID NO:40, does not reasonably provide enablement for trimeric polypeptide complexes comprising a TTSE having 68%, 75%, 81%, 87% or 92% identity to SEQ ID NO:40 or a monomer polypeptide construct comprising a TTSE having 68%, 75%, 81%, 87% or 92% identity to SEQ ID NO:40. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant specification teaches SEQ ID NO:40 as the motif present in trimerizing structural elements. Claims drawn to variants of this motif encompass amino acid substitutions of the residues defined by the motif at specific locations. One of skill in the art would be subject to undue experimentation without reasonable expectation of success in order to make the broadly claimed variants which would function as a trimerizing structural element because such variants would different in amino acid sequence from that of the motif sequence, and it would not be expected that the claimed structural element would tolerate said substitutions and function as trimerizing structural element.

Claims 73, 75-77, 117 and 119-121 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

All other rejections and objections as set forth or maintained in the previous Office action are withdrawn in light of applicants amendments.

Art Unit: 1643

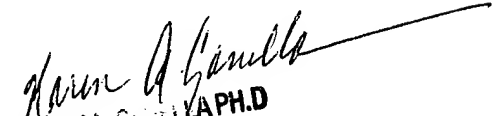
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 11 am to 10 pm, except Wed, Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.

12/12/05

  
KAREN A. CANELLA PH.D.  
PRIMARY EXAMINER